



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

m3570n

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

March 23, 2000

00-PHI-14

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Harold A. Longnecker, Owner  
Sparkling Springs Farm  
RD #2  
Williamsburg, PA 16693

Dear Mr. Longnecker:

On February 15, 2000 Food and Drug Administration (FDA) Investigator Gregory E. Beichner conducted an inspection of your dairy farm in response to United States Department of Agriculture (USDA) reports regarding violative drug residues in four (4) cows you offered for slaughter for human food during the past year. Additional investigation by the FDA at [REDACTED] and [REDACTED]

PA, has revealed serious violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection determined that since May 1999 you have sold the following medicated cows to [REDACTED] without informing the firm regarding their medication status. As a result these animals were purchased by the referenced facilities and were slaughtered for human food.

<u>Back Tag</u>	<u>Slaughter Date</u>	<u>Slaughterhouse</u>	<u>Residue (ppm)</u> <u>Kidney Tissue</u>	<u>Tolerance (ppm)</u>
1378	8/24/99	[REDACTED]	Gentamicin: 1.70 Penicillin: 1.70	0 0.05
23DH8634	7/20/99	[REDACTED]	Gentamicin: 3.60	0
23DH7696	7/01/99	[REDACTED]	Gentamicin: 6.10	0
23DH7699	7/01/99	[REDACTED]	Gentamicin: 4.40	0
737	5/20/99	[REDACTED]	Gentamicin: 3.30	0

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United States Department of Agriculture (USDA) testing revealed the presence of violative gentamicin and penicillin residues in the kidney tissues of your animals. Gentamicin is not approved for oral or injectable use in cattle, and therefore, there is no tolerance for the presence of this drug in edible bovine tissue. The tolerance for penicillin in edible bovine tissue is 0.05 ppm. The presence of gentamicin and penicillin in the edible tissues from your animals renders the food from the animals adulterated.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system to assure that animals have been treated with drugs which have been approved for use in those species, that drugs are not used in a manner contrary to the directions contained in the labeling, and that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

Under the Food, Drug, and Cosmetic Act (the Act), use of a drug in a manner different from that set forth in the approved labeling would cause the drug to be adulterated. Until recently, FDA would permit the extra-label use of approved drugs in food-producing animals under very specific criteria as a discretionary policy. That policy required an extra-label use decision to be made by a veterinarian based on a valid veterinarian/client/patient relationship and other factors, and could not result in a residue in edible animal tissue. The Animal Medicinal Drug Use Clarification Act (AMDUCA) passed by Congress in October 1994 and the implementing regulations which were effective December 9, 1996, permit the extra-label use of approved human and veterinary drugs in food-producing animals only under very specific criteria as a matter of law rather than as a discretionary policy. Under AMDUCA, extra-label use must be by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and that use may not result in any residue which may present a risk to the public health. The decision to use a product in an extra-label manner may not be made by a layperson.

Our inspection determined that the referenced cows were treated with gentamicin and/or penicillin without veterinary guidance or direction and without adherence to prescribed withdrawal times.

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The FDA is also aware of another medicated cow, tag #6081, which was offered for slaughter for human food at [REDACTED]. The cow was slaughtered on or about December 22, 1998 and subsequent USDA testing revealed 3.00 ppm streptomycin in its kidney tissue. The tolerance for streptomycin in edible bovine tissue is 2.0 ppm, and, as a result, this residue renders the food from this animal adulterated.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

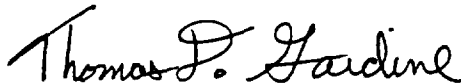
You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violation and prevent its recurrence.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely,



Thomas D. Gardine  
District Director  
Philadelphia District

jci

Enclosure: Title 21 Code of Federal Regulations, Part 530,  
Extra Label Drug Use in Animals

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cc: Dr. John I. Enck, Director  
PA Department of Agriculture  
Bureau of Animal Health and Diagnostic Services (BAHDS)  
2301 North Cameron Street  
Harrisburg, PA 17120

cc: Food Safety and Inspection Service (FSIS)  
106 South 15th Street  
Suite 904  
Omaha, Nebraska 68102  
Attention: Residue Staff